MAY 1 6 2001

SUMMARY PREMARKET 510(k) NOTIFICATION
For UniGlove Polymer Coated Powder-Free Latex Examination Gloves with Protein Content labeling Claim (50 micrograms or less)
510(k) Number: **K010881**

Submission Applicant:

N.S. Uni-Gloves Sdn. Bhd.
Lot 3 & 4/4510 Senawang Industrial Estate,
70450 Seremban, Negeri Sembilan
Malaysia

Telephone No. 60-6-677-2751/2
Fax No. 60-6-677-2755

Registration No. **8040880**
Devise Listing No. **B 034616**
510(k) Number: K010881

Official Correspondent in the United States:

Robert D. Vander Leek, President
UG Healthcare (USA) Inc.
2420 Carson St., Suite 125
Torrance, CA 90501

Telephone No.: (310) 328-7981
Fax No.: (310) 328-7829

Submitted: May 1, 2001

Description of the Device

Trade Name: UniGlove Polymer Coated Powder-Free Latex Examination Glove
Common Name: Examination Gloves
Classification Name: Patient Examination Glove (per 21 CFR 880.6251)
Class I Polymer Coated Powder-Free Latex examination glove 80LYY that meets all of the requirements of ASTM Standard D 3578 – 00

Intended Use of the Device: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Technological Characteristics:

Material: Latex **Cuff:** Beaded **Powder Residue:** Maximum 2mg/glove

Quality Assurance: In compliance with ASTM D3578-00, EN 455-2 : 1995, EN 455-1 : 1993, ISO 2859-1:1989 and manufactured under GMP.

Inspection Parameters:

Criteria	Inspection Level	AQL
Dimensions	S-2	4.0
Physical Properties	S-2	4.0
Water Tight Test 1000ml	G-1	1.5
Visual Major Defects	G-1	1.5
Visual Minor Defects	G-1	2.5

Physical Properties:

Dimensions:

Overall Length:	240 mm minimum
Width:	95 mm minimum (for medium glove)
Palm Thickness:	0.15 to 0.20 mm (at center of palm)
Finger Thickness:	0.17 to 0.25 mm (at 15mm from tip of center finger)
Cuff Thickness:	0.10 to 0.15 mm (at 40mm from the beaded end)

	BEFORE AGING	AFTER AGING
Tensile Strength:	21. Mpa minimum	16.0 Mpa minimum
Ultimate Elongation:	700% minimum	500% minimum
Pinhole AQL	1.5 minimum	1.5 minimum

Packaging: 100 pcs per dispenser box, 10 boxes per case, 1,000 gloves per case

Conclusion: The UniGlove Polymer Coated Powder-Free Latex Examination Glove meets the physical property requirements of ASTM D 3578-00 and the FDA 1000 ml water test both before and after aging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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N.S. Uni-Gloves SDN. BHD.
C/O Mr. Robert D. Vander Leek
Official Correspondent
UG Healthcare (USA), Incorporated
2420 Carson Street, Suite 125
Torrance, California 90501

Re: K010881
Trade/Device Name: UniGlove Polymer Coated Powder-Free Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: May 1, 2001
Received: May 3, 2001

Dear Mr. Vander Leek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): 010881

Device Name: UniGlove Polymer Coated Powder-Free Examination Gloves With Protein Content Labeling Claims (50 MICROGRAM OR LESS)

Indications For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010881